



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,401	10/16/2001	Jose L. Francese	6530.0145-01	3026

22852 7590 05/04/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER
----------

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
----------	--------------

3735

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/977,401

Applicant(s)

FRANCESE ET AL.

Examiner

Charles A. Marmor, II

Art Unit

3736

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

Art Unit: 3736

### **DETAILED ACTION**

1. This Office Action is responsive to the Request for Reconsideration filed February 1, 2006. The Examiner acknowledges Applicant's Remarks. Claims 1-24 are pending.

#### ***Response to Amendment***

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The present application attempts to claim the benefit of the earlier filing date of parent applications U.S. Patent Application Serial Nos. 09/079,168 and 08/756,260.

However, the claimed suction adapter of the present application is not fully supported by the disclosure of said parent applications. Therefore, for purposes of examination the

Art Unit: 3736

earliest effective filing date of the claimed subject matter of the present application is the October 16, 2001 filing date of the present application.

5. Claims 1-3, 12, 14, 15 and 17-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Schalk. ('980). Schalk teaches a medical control valve assembly including an adaptor comprising a manifold (10) having a port (adjacent reference character 48) that is capable of being used as a suction port and a pair of ports capable of receiving other medical devices. A flexible flow valve (50) is positioned in both a first flow path between a first device port (adjacent reference character 34) and a second device port (adjacent reference character 64) and a second flow path between the first device port (adjacent reference character 34) and the suction port (adjacent reference character 48). The suction port is configured such that it is capable of connecting to a suction source. A first device port (adjacent reference character 34) is configured such that it is capable of accommodating an endoscope. The second device port (adjacent reference character 64) is configured such that it is capable of accommodating a suction control device (76). The flexible flow valve (50) is a substantially conical or dome-shaped membrane with a pair of flaps (56) and a centrally-located opening that is configured to increase due to fluid flow therethrough (see Figure 4), a difference in pressure at proximal and distal sides of the valve, or due to an application of suction. The manifold preferably includes two separately manufactured components (20, 24). The first component (20) includes the first device port and the second component (24) is substantially a tee-connector that includes the suction port and the second device port. The manifold includes a third device port (adjacent reference character 66) that is configured such that it is capable of

Art Unit: 3736

accommodating a third medical device. A second flexible flow valve (74) may be located at the third device port.

Regarding claims 17-20, it has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

6. Claims 1-3, 12-15, 17-20, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. ('477). Edwards et al. disclose an adaptor (see Figure 8) comprising a manifold (40) having a port (adjacent reference character 84) that is capable of being used as a suction port and a pair of ports capable of receiving other medical devices. A flexible flow valve (86) is positioned in both a first flow path between a first device port (adjacent reference character 82) and a second device port (adjacent reference character 88) and a second flow path between the first device port (adjacent reference character 82) and the suction port (adjacent reference character 84). The suction port is configured such that it is capable of connecting to a suction source. A first device port (adjacent reference character 82) is configured such that it is capable of accommodating an endoscope. The flexible flow valve (86) may be a substantially flat, conical or dome-like membrane having an opening that is configured to increase due to fluid flow

Art Unit: 3736

therethrough, a difference in pressure at proximal and distal sides of the valve, or due to an application of suction.

Regarding claims 17-20, it has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

#### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4-11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. ('477). Edwards et al, as described above, teach a flow valve (86) in form of a duckbill-type valve, although other types of valves are disclosed as suitable for use with the invention (see column 7, lines 26-29). Edwards et al. do not expressly state that the valve membrane has three flaps, that the valve has a plurality of first flaps having a first shape that alternate with a plurality of second flaps that have a second shape differing from the first shape, or that the valve is multi-prism shaped. Applicant has not disclosed that using a flow valve configured in such a fashion solves any stated problem

Art Unit: 3736

or is for any particular purpose. Moreover, it appears that the flow valve of Edwards et al, or applicant's invention, would perform equally well with any type of flexible flow valve configuration.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Edwards et al. to use a valve having three flaps, a valve having a plurality of first flaps with a first shape that alternate with a plurality of second flaps that have a second shape differing from the first shape, or a valve having a multi-prism shape because such modifications would have been considered mere design considerations which fail to patentably distinguish over Edwards et al.

#### *Response to Arguments*

9. Applicants' arguments, see pages 2-5 of the Request for Reconsideration filed February 1, 2006, with respect to the rejections of claims 1-4, 8, 12, 13 and 17-24 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,929,235 to Merry et al. and of claims 5-7, 9-11 and 14-16 under 35 U.S.C. 103(a) as being unpatentable over Merry et al. have considered but are moot in view of the new grounds of rejection. Applicant persuasively contends that Merry et al. teaches away from fluid flow paths between the various ports, as the purpose of the introducer is to prevent the passage of blood therethrough. The rejections citing Merry et al. have been withdrawn in favor of the new grounds of rejection set forth above citing Schalk or Edwards et al.

With regard to the rejections of claims 5-7, 9-11 and 14-20, Applicants further state that Applicants do not necessarily agree with comments regarding the nature of

Art Unit: 3736

dependent claims 17-20 or the section 103 rejection of dependent claims 5-7, 9-11 and 14-16 set forth in the most recent Office Action and decline to subscribe to any statement or characterization in the Office Action. Since Applicants fail to set forth any specific reasons why these characterizations and rejections are improper, similar rejections have been set forth in this Office Action.

### ***Conclusion***

10. Applicant's amendment of April 25, 2005 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

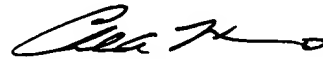
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).



Art Unit: 3736

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

cam  
April 28, 2006